REMARKS/ARGUMENTS

In the Claims:

Claims 1-211 remain pending in the present application. Claims 1, 22, 43, 68, 93, 110, 129, 163 and 186 have been amended to more clearly describe the subject matter recited therein.

Rejection of Claims 1-20, 22-41, 43-66, 68-91, 110-142, 145-152, 163-184, and 186-210 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-20, 22-41, 43-66, 68-91, 110-142, 145-152, 163-184, and 186-210 under 35 U.S.C. § 102(b) as being anticipated by Scahll et al. (US 5,824,111). As Applicant does not believe Schall et al. (Schall) to teach the subject matter of the rejected claims, the rejection is respectfully traversed.

At the outset, Applicant notes that it had difficulty finding support for certain of the Examiner's assertions at the specified locations in Schall. For example, the Examiner asserts that Schall, at column 2, lines 52-54, teaches the use of a plurality of spaced-apart image detectors. However, this section of Schall states only that a digital representation of a patient's residual limb is obtained – there is no recitation of a specific device for accomplishing this. Similarly, the Examiner asserts that Schall, at column 5, lines 21-28, and column 5, lines 15-28, teaches a custom mold component in the form of a mold core and a mold cavity, respectively. However, this section of Schall describes only the carving of a positive socket blank. There is no mention of a mold core or a mold cavity. In fact, based on the manufacturing process taught by Schall, no mold is used (see below). Further still, Applicant can find absolutely no mention in

Schall of the use of a block copolymer material or a fabric outer covering – not in column 5, lines 38-50 or column 7, lines 48-60, as specified by the Examiner, or anywhere else in the reference. If the Examiner maintains these rejections subsequent to consideration of the above amendments and the following remarks, clarification regarding the locations of support for the Examiner's assertions is respectfully requested.

Applicant also notes that the listing of rejected claims beginning on the last line of page 3 of the Office Action appears to be in error. As the Examiner does not assert Schall to anticipate independent claim 153, it cannot anticipate claims 157-158 that depend therefrom.

There appear to be substantial differences between the teachings of Schall and the present invention as recited in the rejected claims. Although Applicant does not believe Schall to read on the claims as filed, in an effort to expedite allowance, Applicant has nonetheless amended certain of the claims to more clearly recite the subject matter of the present invention.

Schall is directed to a system and method for fabricating a *rigid* prosthetic *socket*. To this end, Schall obtains the shape of an amputee's residual limb and then carves a positive likeness (blank) of the residual limb that can be used to create a properly fitting socket.

The manufacturing process taught by Schall is vacu-forming. That is, the carved blank is affixed to a table, an existing rigid plastic preform cone of preselected size is heated and then lowered over the blank, and the preform cone is drawn against the blank by vacuum in order to mimic the shape of the residual limb.

In such a vacu-forming process, the thickness of the formed socket is controlled by adjusting the amount by which the preformed cone is drawn beyond the proximal end of the blank. More specifically, the farther the preformed cone is stretched, the thinner will be the finished socket. Consequently, the major focus of Schall is to precisely control the thickness of the finished socket by using CAD/CAM software to accurately determine to what extent the preformed cone is to be drawn beyond the proximal end of the blank. Another goal is to provide spacers at the proximal end of the blank so that the extra cone material does not cause wrinkles in the finished socket.

Vacu-forming does not employ a mold. Rather, a sheet or preform (e.g., cone) of material is simply drawn over a blank, cooled and removed. The sheet or preform, itself, actually becomes the finished component (e.g., socket). Consequently, there is no mold core or mold cavity as described with respect to the present invention.

As can be understood from the present specification, the present invention is directed to the manufacture of a custom prosthetic *liner* from a *flexible* polymeric material such as a block copolymer. A prosthetic *liner* is considerably different than a prosthetic *socket*. Whereas a prosthetic socket is rigid in order to properly support an amputee's residual limb and the remainder of a prosthetic limb, a liner is soft and flexible to cushion the residual limb from the forces exerted thereon by the interior of the socket. As such, the manufacture of a liner is also considerably different from a socket.

A prosthetic liner according to the present invention cannot be manufactured by vacu-forming. Rather, such a liner must be dipped (usually repeatedly) into a bath of liquid polymeric material, or it must be formed in a mold that is capable of receiving and containing such a material until it properly solidifies.

As described in the present specification, Applicant currently manufactures several sizes of a "generic" version of such a liner. By generic, it is meant that each liner has a generally uniform shape that will adequately fit the residual limbs of most amputees. However, because it has been realized that an even better fit may often be obtained if the exact configuration of an amputee's residual limb is considered, Applicant has developed the present system and method.

With respect to the molding process, the custom liners are manufactured in substantially the same manner as the generic liners – using a mold. As such, it is necessary to create at least one custom mold component that can account for the peculiarities of the residual limb for which a liner is to be manufactured. This custom mold component forms at least part of a mold for its associated liner.

Because Applicant already possesses molds for generic liners, it was also realized that it would be cost effective to be able to use at least a portion of a generic mold with one or more custom mold components. Consequently, a custom liner mold of the present invention may employ, for example, a generic mold cavity associated with a custom mold core, a generic mold core associated with a custom mold cavity, or both a custom mold cavity and a custom mold core.

This type of molding system and process is simply not considered by Schall and, as such, Schall does not teach a system and method whereby the necessary molding component(s) may be produced. Nor does Schall teach the use of a molding machine.

As mentioned above, Schall also fails to teach certain other specific embodiments of the present invention, such as a system and method for producing a

block copolymer liner, a liner having a fabric outer covering, or a liner containing additives such as anti-microbial substances[1].

Applicant also respectfully disagrees with the Examiner's assertion that Schall teaches the system and method of claims 110-152 or claims 153-162. With respect to claims 110-152, Applicant asserts that there is absolutely no teaching or suggestion in Schall of a system for producing a custom prosthetic liner *that allows an amputee with a residual limb of changed shape and/or size to continue wearing an existing prosthetic socket* (see claims 110-128), or a system for producing a custom prosthetic liner *that allows the residual limb of an amputee to be custom fit to a generic prosthetic socket* (see claims 129-152). Each of these systems takes into account the size and/or shape of an amputee's residual limb, as well as the size and/or shape of the interior of the respective socket. A custom liner can then be produced that allows the residual limb to be properly fit into the socket. With respect to the latter system, it becomes possible to provide a custom limb to socket fit without the need to create a custom socket.

Schall does not teach either of these systems. Schall is concerned only with producing a new custom socket. Further, because Schall is directed to a system and method for producing a rigid socket, neither the system nor method of Schall could be used to accomplish the subject matter of claims 110-152.

Therefore, having identified above several material differences between the teachings of Schall and the subject matter of the rejected claims, Applicant respectfully

[1] Applicant notes that it was unable to locate support for the Examiner's assertion that this embodiment is taught by Schall at column 5, lines 25-29.

submits that Schall cannot support a rejection of claims 1-20, 22-41, 43-66, 68-91, 110-142, 145-152, 163-184, and 186-210 under 35 U.S.C. § 102(b).

Rejection of Claims 21, 42, 67, 92-109, 143, 144 153-162, 185 and 211 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 21, 42, 67, 92-109, 143, 144, 153-162, 185 and 211 under 35 U.S.C. § 103(a) as being unpatentable over Schall in view of Onyshkevych et al. (US 6,665,577). As Applicant does not believe Schall in view of Onyshkevych et al. (Onyshkevych) to teach or suggest the subject matter of the rejected claims, the rejection is respectfully traversed.

The deficiencies of Schall have been discussed at length above. Combining Schall with Onyshkevych does not overcome these deficiencies. More specifically, Onyshkevych does not teach or suggest any type of prosthetic liner molding system or process, little alone the system and process of the rejected claims.

Further, with respect to claims 153-162, Onyshkevych does not teach or suggest an interface for allowing a user of said system to communicate with a separate system and computer program that facilitates the automatic configuration and purchasing of a medical device, nor a storage system for storing said a custom mold component for future use that also includes a means for identifying a particular custom mold component with a particular amputee. Consequently, Onyshkevych cannot overcome the deficiency of Schall with respect to these elements.

Onyshkevych teaches only a system and method for predicting the fit of an *existing* garment based on dimensional data related to the garment and to a potential wearer. (See column 2, lines 38-44). Onyshkevych does not teach or suggest a

system or method by which a medical device, or even a garment for that matter, can be automatically configured (designed) and purchased. As such, Applicant respectfully submits that Schall in view of Onyshkevych cannot support a rejection of claims 21, 42, 67, 92-109, 143, 144, 153-162, 185 and 211 under 35 U.S.C. § 103(a).

CONCLUSION

Applicant has amended claims 1, 22, 43, 68, 93, 110, 129, 163 and 186, and has distinguished the subject matter of the present invention over the teachings of the references cited as prior art by the Examiner.

Therefore, Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

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By: 

Eric M. Gayan
Attorney for Applicant
Registration No. 46,103
Standley Law Group LLP
495 Metro Place South
Suite 210
Dublin, Ohio 43017-5319
Telephone: (614) 792-5555
Facsimile: (614) 792-5536
E-mail:egayan@standleyllp.com